

HIV

HIV VACCINES EXPLAINED



MAKING HIV VACCINES A REALITY



NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
NATIONAL INSTITUTES OF HEALTH

WHAT IS AN HIV VACCINE?

A preventive HIV vaccine is a substance that teaches the body's immune system to recognize and protect itself against HIV — the virus that causes AIDS. All of the HIV vaccines currently being tested in humans are made from man-made materials that cannot cause HIV infection.

Scientists believe that an effective HIV vaccine, given before exposure to HIV, could have a number of possible outcomes. These include:

- Preventing infection in most people
- Preventing infection in some people
- Preparing a person's immune system to block continued infection and eliminate the virus (Vaccines against measles, mumps and polio work this way.)
- Delaying or preventing the onset of illness or AIDS



The goal is to develop a vaccine that is 100 percent effective and protects everyone from infection. However, even if a vaccine only protects some people, it could have a major impact on controlling the epidemic. A partially effective vaccine could decrease the number of people who get infected with HIV; those people, in turn, would not pass the virus on to others. Even when an HIV vaccine is developed, education and other prevention efforts will be needed so that people continue to practice safe behaviors.

HISTORY OF VACCINES

The value of vaccines was recognized approximately 200 years ago, beginning with a vaccine against smallpox. It saved millions of lives, and its success helped people understand that introducing something into the body can actually trigger a protective immune response, and prevent disease.

Today, there are numerous safe and effective vaccines. Vaccines have been used successfully against many life threatening diseases, including eliminating smallpox worldwide, and polio in most of the world.

THE NEED FOR AN HIV VACCINE

The best long-term hope for controlling the AIDS epidemic is the development of safe, effective and affordable preventive HIV vaccines. Consider these facts:

- Every year 40,000 people are newly infected with HIV infection in the United States.
- Approximately 900,000 people in the United States are already infected with HIV.
- Globally, 14,000 people are infected with HIV *every day*, and *each minute* six young people under 25 become infected.
- Over 40 million people are living with HIV around the world.
- To date, over 16 million men, women and children have died from AIDS.



PREVENTIVE VERSUS THERAPEUTIC HIV VACCINES

Multiple HIV vaccines may be necessary to prevent infection or disease in the same way multiple drugs are needed to treat people already infected with HIV.

Preventive HIV vaccines are being developed to control the spread of HIV and are not a cure for AIDS.

Researchers are also evaluating therapeutic vaccines to treat people with HIV infection or AIDS. While the same vaccine may be tested for both preventive and therapeutic effects, what works to prevent HIV infection may not necessarily work to treat people who are already infected with HIV.

IS AN HIV VACCINE AVAILABLE NOW?

Unfortunately, no. Scientists have been studying HIV for over two decades — and continue to make progress. Even when a promising vaccine is discovered, it will take time to test and evaluate its safety and effectiveness.

TESTING HIV VACCINES

Vaccine development requires several years of research in laboratories and animals before clinical testing in humans can begin. A potential vaccine goes through three phases of testing in humans before the Food and Drug Administration (FDA) can consider licensing it for public use. The three phases of clinical tests are:

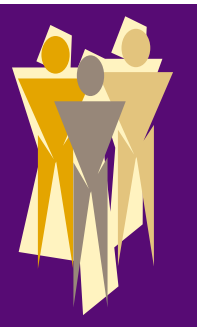
- **Phase I** — involves a small number of healthy volunteers (HIV-negative and at low risk for HIV infection) to test the safety and various doses of the vaccine; usually lasts 12 to 18 months
- **Phase II** — involves hundreds of volunteers (HIV-negative and both low- and high-risk populations) to test the safety and immune responses of the vaccine; can last up to 2 years
- **Phase III** — involves thousands of volunteers (HIV-negative and high-risk populations) to test the safety and effectiveness of the vaccine; can last 3 to 4 years

Throughout all phases of human testing, an independent review board regularly monitors the study to ensure the safety of the volunteers.

PHASE I

12 to 18 Months

Small group of healthy, low-risk participants



PHASE II

Up to 2 years

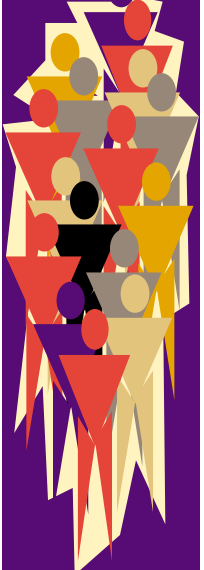
Hundreds of high- and low-risk participants



PHASE III

3 to 4 Years

Thousands of high-risk participants



PROTECTING RESEARCH PARTICIPANTS

HIV vaccine clinical trials are completely voluntary. Researchers are required to obtain the “informed consent” of all participants to make sure they fully understand the purpose of the study, how the HIV vaccine will be tested, the number of clinical visits required and the possible benefits and side effects caused by the vaccine.

So far, few side effects have been associated with experimental HIV vaccines. Those that have occurred have been mild and similar to those of any other approved vaccines. The most common side effects are soreness at the site of the injection, a low-grade fever, and body aches, which quickly disappear. Throughout the study, volunteers are carefully examined to determine if there are any serious side effects associated with the vaccine.

After a volunteer receives an HIV vaccine it’s possible to test positive for HIV antibodies on a standard HIV test (i.e., ELISA) because the vaccine triggers the body to produce antibodies to prevent infection. The HIV vaccines being tested in humans do not contain HIV; therefore, they cannot cause HIV infection. Other tests are available at the study sites to determine whether a volunteer is actually infected with HIV. If volunteers engage in behaviors that expose them to HIV outside of the study, they may become infected with HIV.

It is rare for volunteers to encounter problems as a result of testing positive for HIV antibodies. However, volunteers could potentially experience problems donating blood, getting insurance, traveling to other countries or getting employment. All volunteers are given an identification card to show they are part of the study, and designated research staff are available to address any issues that may arise.



COMMUNITY PARTICIPATION IN VACCINE RESEARCH

By raising awareness and encouraging study participation, individuals and communities can contribute to the successful development of HIV vaccines. Although thousands of people have already volunteered to take part in HIV vaccine studies, many more are needed. A large HIV vaccine trial will require thousands more participants of all races, genders and socioeconomic backgrounds to determine if the vaccine affects people differently.

Community support is essential, and efforts continue to break down stigmas and myths about vaccine research. Developing an effective HIV vaccine depends upon individuals and communities informing, educating and supporting others.

HOW TO HELP

- Let others know you support HIV vaccine research.
- Educate others about the need for an HIV vaccine.
- Support vaccine trial volunteers and/or volunteer yourself!

The National Institute of Allergy and Infectious Diseases (NIAID), at the National Institutes of Health (NIH), supports a comprehensive program of HIV vaccine research.

For more detailed information about HIV vaccines and study sites, please contact the NIAID at

WWW.NIAID.NIH.GOV/AIDSVACCINE

or contact NIAID's HIV Vaccine Trials Network at

WWW.HVTN.ORG

Or call **1-800-Trials-A.**

PARA MÁS INFORMACIÓN EN EL ESPAÑOL ACERCA DE
VACUNAS DE SIDA,
LLAME: **1-800-Trials-A.**